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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

August 12, 1999

WARNING LETTER NO. 99-NOL-40

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Sam P. Scelfo, Jr., Owner and President
Gambino's Bakeries, Inc.
3609 Toledano Street
New Orleans, Louisiana 70125

Dear Mr. Scelfo:

The U.S. Food and Drug Administration (FDA) made an inspection of your firm on April 14-16, 19-20, and 30, 1999. Our investigators documented numerous insanitary conditions in your bakery that showed food products had been held in a facility whereby they may become contaminated with filth. Preparing, packing, or holding food under insanitary conditions renders the food adulterated under section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the food may become contaminated with filth.

The objectionable conditions documented include:

1. Three live rodents observed in several areas in the warehouse area;
2. One dead rodent observed in a rodent trap behind pallets of [redacted] in the warehouse area;
3. Two bags of [redacted] with fluorescing stains characteristic of rodent urine;
4. Five cans of artichoke hearts containing six rodent excreta pellets on the can's outside surface;
5. One cardboard case of bags of unlabeled bread crumbs with rodent excreta pellets and fluorescing stains characteristic of rodent urine;
6. Rodent excreta pellets on the floor and on the food preparation table in the Salad Preparation Room;
7. Numerous rodent excreta pellets on the mixing room floor, and near pallets of [redacted] and Confectioners sugar;
8. One rodent excreta pellet on an employee apron that was on a plastic crate stacked outside of the mixing room;

9. Moldy bakery dough, decaying cream cheese, decomposed eggs in the cooler near the baking room;

10. One pail of jar neck seals, with foreign black residues on the outside surface, and placed on the food preparation table near the food grinder; and,

11. Dark orange and black residues from previous operations on the food grinders.

Investigation of the general storage conditions in the warehouse revealed a 1½ inch wide opening along the bottom of the 13-foot long receiving door that may provide an entry for rodent vermin. A large hole was observed in the ceiling in the warehouse, and a rodent had departed through this hole.

At the close of the inspection, you reported you had or would discard food products containing rodent excreta pellets. On May 11, 1999, you sent FDA a letter that listed the food products voluntarily destroyed by your firm during the week of April 14 –21, 1999. Further corrections were promised, however, these corrections have not been verified.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to insure that your facility is operated in a sanitary manner.

At the conclusion of the inspection, the FDA investigators presented to you a list of deficiencies on Form FDA-483, List of Inspectional Observations. You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, please state the reason for the delay and the time by which the corrections will be completed.

Additionally, the investigators documented that your firm manufactures an olive salad preparation and a marinated vegetable relish. These food products may be considered acidified or low acid canned foods and would be required to comply with Title 21 CFR Parts 108, 113, 114 and other requirements of the Act. The Act requires manufacturers of acidified or low acid canned foods to register their processing plant, and file the manufacturing processes with the FDA. A copy of these regulations is enclosed.

Your response should be directed to Patricia K. Schafer, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Schafer at her telephone number (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483 and Acidified and Low Acid Canned Food Regulations